

QA-RA Engineer

[Breast cancer](#) is the most frequently diagnosed cancer and second cause of cancer death among women. In many countries women are encouraged to begin routine mammography screening exams to detect cancer as early as possible. Early detection and diagnosis has been shown to improve outcomes for patients. However, this requires a large number of radiologists to analyze all the images, and a lot of countries do not have enough experienced breast radiologists to meet the demand.



1 in 8 women affected during her lifetime



Every 1000 women screened, 5 will have breast cancer.
But 100 will be recalled for further testing.

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We can do better!

[Therapixel](#) is a spin-off Inria created in 2013 specialized in medical imaging with 15 employees. We are renowned for winning the [Digital Mammography DREAM Challenge](#) [1,2], a world-wide competition organized to improve the state-of-the-art in automatic mammography screening. Recently, we successfully closed a 5M€ series-A fundraise to accelerate the development of a product for improving breast cancer screening.

Job description: As a Quality and Regulatory Engineer you will be responsible for developing and maintaining procedures and activities within Therapixel's quality management system (QMS). You will be expected to help define regulatory strategy and ensure Therapixel's compliance with applicable regulations and standards. This will require coordinating across teams, so effective communication skills are important. You will be expected to update, review and create new procedures, which will require the ability to write clear and concise English.

Key responsibilities include:

- Maintaining the quality management system for Therapixel in compliance with ISO 13485 and 21 CFR pt820.
- Act as the point of contact for regulatory bodies such as the ANSM and FDA.
- Ensure compliant products are delivered.
- Manage post-market activities such as vigilance, surveillance and reporting.
- Maintaining and coordinating the Management Review process, including routine reporting.
- In charge of overseeing risk management for Therapixel.
- In charge of information security for Therapixel.
- Define regulatory strategy for Therapixel products in collaboration with top management.

- Continuously monitor and communicate regulatory changes that impact Therapixel.
- Responsible for Therapixel's compliance with applicable Quality and Information Security standards.
- Managing non-conformities (NCs) and associated corrective and preventive actions (CAPA).
- Coordinate with all business areas involved in the software development lifecycle, from research, through design and maintenance, sales and after-sales.
- Preparing regulatory submissions for software medical devices.
- Coordinating internal audits and liaising the Notified Bodies for external audits.

Additional duties include:

- Resource planning to meet agreed goals.
- Defining and reporting on key performance indicators.
- Providing guidance and assistance to all employees on quality and compliance issues.
- Assessing complex problems and clearly articulating solutions.

Why work at Therapixel?

- Become part of a renowned, dynamic and eager team; learn from the best, but teach them too – we're curious and eager to learn from you!
- Make sure your work will have a longstanding and positive impact on healthcare;
- Work in a collaborative environment: we have team members dedicated to research, regulatory affairs (FDA/CE), and clinical partnerships.

Desired candidate skills and experience:

- Knowledge and experience of medical device standards and regulations, especially applied to software:
 - ISO 13485
 - ISO 14971
 - IEC 62304, IEC 62366
 - US regulations: 21 CFR Part 820 Quality System Regulations
- Knowledge and experience of EU medical device regulation (MDD / MDR) and US medical device regulations (FDA).
- Degree in a health or engineering field.
- 5 or more years of experience in quality management.

Conditions:

Contract type:	Permanent Contract
Location:	Sophia Antipolis (Alpes Maritimes, France)
Benefits :	36 days of paid holidays, sponsored cafeteria on site, health insurance
Salary :	Competitive and negotiable

How to apply:

Please send your resume and motivation letter to jobs@therapixel.com . Please include **[job-qara]** in the subject.

Join Therapixel – help in building the medicine of the future



References:

[1] DM Challenge Yaroslav Nikulin (Therapixel) write up.

Available: <https://www.synapse.org/#!Synapse:syn9773040/wiki/426908>.

[2] Therapixel Press Release <https://goo.gl/BSG6rZ>

